Paper No. 46

## UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT E. WEINSTEIN and ALAN M. WEINSTEIN

Appeal No. 2002-1404 Application No. 08/891,918

ON BRIEF

Before ABRAMS, McQUADE, and NASE, <u>Administrative Patent Judges</u>. NASE, <u>Administrative Patent Judge</u>.

#### **DECISION ON APPEAL**

This is a decision on appeal from the examiner's final rejection of claims 21, 26, 29 and 34, which are all of the claims pending in this application.<sup>1</sup>

We REVERSE.

<sup>&</sup>lt;sup>1</sup> Claim 21 was amended subsequent to the final rejection. While the examiner has approved entry of the amendment after final rejection (Paper No. 32, filed April 12, 2001), we note that this amendment has not been clerically entered.

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### **BACKGROUND**

The appellants' invention relates to a medicinal package that improves compliance with the treatment regimen prescribed for sinusitis (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Cappuccilli	4,039,080	Aug. 2, 1977
Knudsen	4,295,567	Oct. 20, 1981
D'Amico et al. (D'Amico)	5,788,974	Aug. 4, 1998
Jacobus et al. (Jacobus)	5,789,391	Aug. 4, 1998
Russell et al. (Russell)	5,827,852	Oct. 27, 1998

In addition, the examiner took Official Notice of the conventional use of providing instructional material with medication.

Claims 21, 26, 29 and 34 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jacobus in view of Russell, D'Amico and Official Notice.

Claims 21, 26, 29 and 34 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jacobus in view of Russell, Cappuccilli, Knudsen and Official Notice.

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Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the answer (Paper No. 37, mailed August 29, 2001) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 36, filed July 20, 2001) and reply brief (Paper No. 38, filed October 19, 2001) for the appellants' arguments thereagainst.

#### <u>OPINION</u>

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art, to the evidence of nonobviousness that is of record in this application (e.g., the declaration of Dr. David Kennedy, various journal articles, etc.) and to the respective positions articulated by the appellants and the examiner. Upon evaluation of all the evidence before us, it is our conclusion that the evidence adduced by the examiner is insufficient to establish a case of obviousness with respect to the claims under appeal.<sup>2</sup> Accordingly, we will not sustain the examiner's rejection of claims 21, 26, 29 and 34 under 35 U.S.C. § 103. Our reasoning for this determination follows.

<sup>&</sup>lt;sup>2</sup> In rejecting claims under 35 U.S.C. § 103, the examiner bears the burden of presenting a case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

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When it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation in the prior art to make the selection made by the appellants. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. The extent to which such suggestion must be explicit in, or may be fairly inferred from, the references, is decided on the facts of each case, in light of the prior art and its relationship to the appellants' invention. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the appellants' structure as a template and selecting elements from references to fill the gaps. The references themselves must provide some teaching whereby the appellants' combination would have been obvious. In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (citations omitted).

Evidence of a suggestion, teaching, or motivation to modify a reference may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), Para-Ordinance Mfg., Inc. v. SGS Importers Int'l., Inc., 73 F.3d 1085, 1088, 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), cert. denied, 117 S. Ct. 80 (1996),

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although "the suggestion more often comes from the teachings of the pertinent references," In re Rouffet, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). The range of sources available, however, does not diminish the requirement for actual evidence. A broad conclusory statement regarding the obviousness of modifying a reference, standing alone, is not "evidence." Thus, when an examiner relies on general knowledge to negate patentability, that knowledge must be articulated and placed on the record. See In re Lee, 277 F.3d 1338, 1342-45, 61 USPQ2d 1430, 1433-35 (Fed. Cir. 2002). See also In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

In our view, the combined teachings of the applied prior art would not have made it obvious at the time the invention was made to a person of ordinary skill in the art to have prepared a prepackaged blister pack for providing a therapeutic regimen lasting at least ten days for treating sinusitis which incorporates (1) a plurality of dosages of an oral antibiotic effective for treating sinusitis caused by at least one of the organisms from the class consisting of Streptococcus pneumoniae, Haemophilis influenza, and Moraxella catarrhalis; (2) a plurality of dosages of at least one active treatment oral medication selected from the class consisting of decongestant, expectorant, mucolytic, anti-inflammatory agent, cell stabilizer, and mediator antagonist; and (3) instructions for coordinating use of the dosages together. In that regard, we see no motivation,

suggestion or teaching in the combined teachings of the applied prior art, absent the use of impermissible hindsight,<sup>3</sup> for an artisan to have applied the blister pack teachings of either Knudsen<sup>4</sup> or D'Amico<sup>5</sup> to the known regimen for treating sinusitis (e.g., Jacobus). In that regard, we note that, at most, the combined teachings of the applied prior art may have suggested that one skilled in the art might have found it obvious to try using a prepackaged blister pack which incorporates dosages for providing a regimen for treating sinusitis. But whether a particular combination might be "obvious to try" is not a legitimate test of patentability. See In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988); In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 379

<sup>&</sup>lt;sup>3</sup> Hindsight knowledge derived from the appellants' own disclosure to support an obviousness rejection under 35 U.S.C. § 103 is, of course, impermissible. <u>See, for example, W. L. Gore and Assocs.</u>, <u>Inc. v. Garlock, Inc.</u>, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), <u>cert. denied</u>, 469 U.S. 851 (1984).

<sup>&</sup>lt;sup>4</sup> Knudsen discloses a pharmaceutical dispensing container which holds two dosage units which are symptomatic treatments for respiratory tract disorders, the first of these dosage units being indicated for day-time administration and being non-sedative and the second of these dosage units being indicated for night-time administration and being sedative. Knudsen contains no teaching or suggestion to apply the invention to any other treatment regimen. Thus, Knudsen's invention pertains only to treatment of respiratory tract disorders.

<sup>&</sup>lt;sup>5</sup> D'Amico discloses a pharmaceutical dispensing container which holds multiple dosage units for aiding in the compliance in the eradication/treatment for *Helicobater pylori* and subsequent/related gastric maladies in relation to said bacterial infection using a repetitive dosage regimen for a treatment period of sufficient duration to mitigate said bacterial infection formatted in such a way to gain optimal ease of compliance resulting in improved outcome of treatment. D'Amico contains no teaching or suggestion to apply the invention to any other treatment regimen. Thus, D'Amico's invention pertains only to treatment of *Helicobater pylori* and subsequent/related gastric maladies.

(Fed. Cir. 1986); In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977). Moreover, the declaration of Dr. Kennedy and the other evidence of non-obviousness of record in this application cited in the brief (pp. 20-28) clearly outweigh any evidence of obviousness contained in the teachings of the applied prior art.

For the reasons set forth above, the subject matter of claims 21, 26, 29 and 34 is not suggested by the applied prior art. Accordingly, the decision of the examiner to reject claims 21, 26, 29 and 34 under 35 U.S.C. § 103 is reversed.

# **CONCLUSION**

To summarize, the decision of the examiner to reject claims 21, 26, 29 and 34 under 35 U.S.C. § 103 is reversed.

## **REVERSED**

NEAL E. ABRAMS Administrative Patent Judge	) ) )
JOHN P. McQUADE Administrative Patent Judge	) ) BOARD OF PATENT ) APPEALS ) AND ) INTERFERENCES )
JEFFREY V. NASE	) )

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